JUN 2 1 2002

K021714

510(k) Summary of Safety and Effectiveness
[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:	PLUS ORTHOPEDICS 6055 Lusk Blvd. San Diego, CA 92121 Tel: 858-550-3800 x 2506 Attn: Mr. Hartmut Loch, RAC Director, Regulatory Affairs
Trade name:	RT-PLUS™ Knee System
Common name:	Hinged Knee Prosthesis
Classification name:	Prosthesis Knee, Femorotibial, Constrained, Cemented, Metal/Polymer § 888.3510 - Class II - Product Code: KRO - 87 Orthopedic Device Panel
Predicate Device:	RT-PLUS™ Knee System, K003504 - S/E 5/11/01
Device Modification Description:	The snapping mechanism of the PE tibial inserts for the RT-PLUS™ Knee System (S/E May 11, 2001 – K003504) has been modified by adding a clamp to secure the PE insert to the tibial component. All PE tibial inserts of the predicate device have been modified, and they are available in sizes 2, 4, 6, 8 and 10, and each size in 8 mm, 11 mm, 14 mm and 17 mm height.
Indications:	The RT-PLUS™ Knee System is a tri-compartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use as a replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The RT-PLUS™ Modular Cemented Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Biomechanical tests have been performed. The test results of the modified components were superior to the predicate device and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2002

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, CA 92121-2700

Re: K021714
Trade/Device Name: RT-PLUS™ Knee System
Regulation Number: 21 CFR §888.3510
Regulation Name: Knee joint femortibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: May 21, 2002
Received: May 23, 2002

Dear Mr. Loch;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K021714

Device Name(s): RT-PLUS™ PE Insert Clamp

Indications for Use:

The RT-PLUS™ Knee System is a tri-compartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use as a replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The RT-PLUS™ Modular Cemented Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021714